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APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE CONFIRMATION NO. 09/18/2001 09/936,845 05407.00003 Johnathan A. Napier 1445 22907 7590 10/03/2003 EXAMINER **BANNER & WITCOFF** MCELWAIN, ELIZABETH F 1001 G STREET N W PAPER NUMBER ART UNIT **SUITE 1100** WASHINGTON, DC 20001 1638

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application	n No.	Applicant(s)	
		09/936,848	5	NAPIER, JOHNATHAN A.	
		Examiner		Art Unit	
		Elizabeth F		1638	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status					
1)[🛛	Responsive to communication(s) filed on <u>9/18/02</u> .				
2a) <u></u> □	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)[	Claim(s) <u>1-43</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.				
<b>5</b> \□	Claim(s) is/are allowed.				
•	•				
	Claim(s) is/are objected to.				
8) Claim(s) 1-43 are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12)☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No				
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
1)  Notic 2)  Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	í		ary (PTO-413) Paper No(s) al Patent Application (PTO-152)	

Art Unit: 1638

## Page 2

## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-15, 35 and 37 drawn to a polypeptide and pharmaceutical compositions comprising said polypeptide, classified in class 530, subclass 350, for example.
  - II. Claims 16, 17, drawn to DNA encoding a PUFA elongase, classified in class536, subclass 23.1, for example.
  - III. Claims 18-20, drawn to an engineered mammalian organism that expresses a polypeptide, classified in class 800, subclass 13, for example.
  - IV. Claims 21, 22, 24 and 25, drawn to an organism engineered to express a synthetic pathway, classified in class 800, subclass 13, for example.
  - V. Claim 26, drawn to an engineered fish, classified in class 800, subclass 20.
  - VI. Claims 27 and 28, drawn to a transgenic plant engineered to express a polypeptide, classified in class 800, subclass 298.
  - VII. Claims 29-31, drawn to a method of producing a PUFA by carrying out an elongase reaction, classified in class 435, subclass 4.
  - VIII. Claims 32-34, 36 and 41, drawn to a PUFA and products comprising said PUFA, classified in class 562, subclass 598.
  - IX. Claims 38-40, drawn to a method of elevating PUFA levels by supplying a polypeptide to an animal, classified in class 514, subclass 2.

Art Unit: 1638

X.

Claim 38, drawn to a method of elevating PUFA levels by supplying a

Page 3

polypeptide to a plant, classified in class 514, subclass 2.

XI. Claim 42, drawn to a method of elevation PUFA levels by supplying a DNA

molecule to an animal, classified in class 514, subclass 44.

XII. Claim 42, drawn to a method of elevation PUFA levels by supplying a DNA

molecule to a plant, classified in class 514, subclass 44.

XIII. Claim 43, drawn to a method of elevating PUFA levels by supplying a PUFA to

an animal, classified in class 424, subclass 476.

XIV. Claim 43, drawn to a method of elevating PUFA levels by supplying a PUFA to

a plant, classified in class 424, subclass 476.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-VI and VIII are unrelated. Inventions are unrelated if it can be shown that

they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case

the different inventions are each different products that are chemically, structurally and

functionally distinct, and one is not required by any of the others, wherein the polypeptides and

PUFAs can be made independently from the isolated nucleic acid, such as by extraction or

chemical synthesis, for example.

3. In addition, Inventions VII and IX-XIV are drawn to distinct methods wherein one is

not required by any of the others and each requires different starting materials, different

method steps and results in different products. Furthermore, the products of Inventions I-VI

and VIII are distinct from the methods of Inventions VII and IX-XIV, wherein each product

Art Unit: 1638

can be used in another method as exemplified by the alternate methods provided. For example

Page 4

the PUFA can be used to produce a foodstuff or for supplying to an animal.

4. Because these inventions are distinct for the reasons given above and have acquired a

separate status in the art as shown by their different classification, restriction for examination

purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention,

the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR

1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Elizabeth F. McElwain whose telephone number is 703-308-

1794. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the

organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth F. McElwain

Primary Examiner

Art Unit 1638

Art Unit: 1638

EFM

Page 5